UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NATIONAL JOINT POWERS ALLIANCE, on behalf of itself and all others similarly situated,

Plaintiffs.

v.

ASTRAZENECA AB, a Swedish Corporation, AKTIEBOLAGET HASSLE, a Swedish Corporation, ASTRAZENECA LP, a Delaware Limited Partnership, and ASTRAZENECA PHARMACEUTICALS, LP, a Delaware Limited Partnership.

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Civil Action No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiffs, National Joint Powers Alliance, on behalf of itself and the class of Endpayors as defined below, upon personal knowledge as to facts pertaining to itself, and upon information and belief, and upon the investigation of their counsel as to all other matters, alleges as follows:

NATURE OF ACTION

1. This is a nationwide class action brought under state antitrust laws and consumer protection statutes seeking damages and declaratory relief arising from the manufacture and marketing of the brand-name drug TOPROL-XL®, a drug used in the treatment of angina, hypertension and congestive heart failure. Defendant's unlawful conduct prevented generic versions of TOPROL-XL from entering the United States

market, thereby causing injury to Plaintiff and members of the Class.

- 2. Metoprolol succinate is the generic name for TOPROL-XL. Metoprolol succinate was invented by Aktiebolaget Hassle in the mid 1980's. AstraZeneca LP ("Astra") obtained two patents for "extended release" versions of metoprolol succinate and manufacture it under the brand name TOPROL-XL (the patents are United States Patent 5,001,161 and 5,081,154 (the "'161 Patent" and "'154 Patent" respectively)). This litigation involves Astra's illegal efforts to obtain the '161 and '154 Patents -- efforts that were further complicated by the sham litigation it engaged in with several generic manufacturers to artificially extend the life of the '161 and '154 Patents. As a result of these illegal efforts, Astra precluded generic manufacturers from entering the market and obtained yearly sales in excess of \$1.3 billion in the Unites States alone.
- 3. At least three manufacturers of generic versions of medicines, including KV Pharmaceuticals ("KV"), Andrx Corporation ("Andrx") and Eon Labs, Inc. ("Eon"), filed applications with the Food and Drug Administration ("FDA") requesting approval to manufacture, market and sell a generic versions of TOPROL-XL®. These manufacturers assert in their applications that their respective products are "bioequivalent" to the TOPROL-XL® brand name product and do not infringe any valid patent owned by or licensed to the Astra.
- 4. Astra commenced a baseless patent infringement action against KV, Andrx and Eon in an attempt to thwart production of generic versions of TOPROL-XL® from entering the United States market. Those actions were consolidated in the Eastern District of Missouri in *In re Metoprolol Succinate Patent Litigation*, MDL No. 1620.

Ultimately, the Court found the '161 and '154 Patents invalid because: 1) the patents were barred by the doctrine of double patenting as obvious and anticipated; and 2) the patents were unenforceable based on inequitable conduct Astra engaged in during the prosecution of its patent before the United States Patent Trademark Office ("PTO").

- 5. As a direct and proximate result of Astra's unlawful conduct, End-payors such as those in the class were denied the benefits of free and unrestrained competition in the market. More specifically, Plaintiff and the Class were denied the opportunity to choose between the brand name prescription drugs and lower priced generic versions by being forced to pay supracompetitive prices.
- 6. In Count I of this Complaint, Plaintiffs, on behalf of themselves and all others who are members of the consumer class, seek equitable, injunctive and declaratory relief against Astra based on allegations of monopolization of, and an attempt to monopolize, the market for TOPROL-XL® and its generic bioequivalents, in violation of state indirect purchaser laws including Alaska, Alabama, Arizona, California, the District of Columbia, Florida, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Vermont, West Virginia and Wisconsin (the "Indirect Purchaser States"). Count I is brought pursuant to the antitrust laws of the Indirect Purchaser States.
- 7. Count II seeks recovery for declaratory relief under Section 16 of the Clayton Act for Astra's violation of Section 2 of the Sherman Act.
 - 8. Count III is brought by Plaintiffs on their own behalf and on behalf of the

Class, seeking a constructive trust and disgorgement of the unjust enrichment of Astra.

PARTIES

- 9. Plaintiff, National Joint Powers Alliance (hereinafter "NJPA") is a nonprofit corporation with its principal place of business in Staples, Minnesota. NJPA is a self-funded cooperative which supplies goods and services to school districts, cities, counties, and other government agencies. Plaintiff NJPA is a member of the class defined herein, will adequately represent the interests of the class, and seeks to be certified as Class Representative of this class.
- 10. Defendant AstraZeneca AB ("Astra AB") is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälie. Sweden. This Swedish corporation is engaged in research, manufacture, marketing and sales of pharmaceuticals, including TOPROL-XL®.
- 11. Defendant Aktiebolaget Hassle ("Hassle") is a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal. Sweden. This Swedish corporation is engaged in research, manufacture, marketing and sales of pharmaceuticals, including TOPROL-XL®.
- 12. Defendant AstraZeneca LP ("Astra LP"), is a limited partnership organized under the laws of Delaware with its principal place of business in Wilmington, Delaware. This Delaware limited partnership is engaged in research, manufacture, marketing and sales of pharmaceuticals, including TOPROL-XL®.
- 13. Defendant AstraZeneca Pharmaceuticals ("Astra Pharma"), is a limited partnership organized under the laws of Delaware with its principal place of business in

Wilmington, Delaware. This Delaware limited partnership is engaged in research, manufacture, marketing and sales of pharmaceuticals, including TOPROL-XL®.

- 14. There exists, at all times mentioned, a unity of interest in ownership between Astra AB, Astra Pharma LP and Astra LP such that individuality and seperateness between them has ceased. These Defendants are alter-egos of one another and exerted control over each other. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from one another will permit an abuse of the corporate privilege, would sanction fraud, and promote injustice. Hereinafter, Astra AB, Astra Pharma LP and Astra LP will be referred to collectively through this Complaint as "Astra".
- 15. Various persons, partnerships, sole proprietors, firms, corporations and individuals not named as Astra in this lawsuit, and individuals, the identities of which are presently unknown, may have participated as co-conspirators with Astra in the offenses alleged in this complaint, and have performed acts and made statements in furtherance of the alleged conspiracy to monopolize.

JURISDICTION AND VENUE

16. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. §§ 1332. There is complete diversity of citizenship between Plaintiff and Defendants and the amount in controversy exceeds \$75,000.00, exclusive of interests and costs. Further, jurisdiction exists under 28 U.S.C. §§1337(a) because this action alleges violations arising under the Clayton Antitrust Act of 1914 and Sherman Antitrust Act of 1890. In addition, this Court has jurisdiction over state law claims alleged herein pursuant to 28

- U.S.C. § 1332(d)(2), as amended in 2005 (the Class Action Fairness Act) because the matter in controversy exceeds \$5,000,000 and there is complete diversity of citizenship between Plaintiff and Defendants.
- 17. Venue is proper in this judicial district because Defendants are organized under the laws of this state and have a principal place of business within this district.
- 18. The illegal monopolization and attempt to monopolize the market for TOPROL-XL® and generic versions of TOPROL-XL®, as alleged herein, have substantially affected interstate and foreign commerce.

INTERSTATE TRADE AND COMMERCE

- 19. Astra's efforts to monopolize and restrain competition in the market for TOPROL-XL® substantially affected interstate and foreign commerce.
- 20. During all or part of the Class Period, Astra manufactured and sold substantial amounts of TOPROL-XL® in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Astra maintained an exclusive license to market and sell TOPROL-XL® in the United States by virtue of the illegally obtained '161 and '154 Patents.
- 21. At all material times, Astra manufactured and sold TOPROL-XL® and shipped it across state lines and sold to customers located outside its state of manufacture.
- 22. During all or part of the Class Period (defined below), Astra transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of TOPROL-XL®.

23. In furtherance of its efforts to monopolize and/or restrain competition in the market for TOPROL-XL® and its generic equivalents, Astra employed the United States mail, interstate and international telephone lines, as well as means of interstate and international travel.

RELEVANT MARKET

- 24. During the class period, the relevant market is the manufacture and sale of TOPROL-XL® (metoprolol succinate) sold in the United States. The relevant geographic market for TOPROL-XL® is the United States.
- 25. During the class period, Astra's share of each relevant market was 100%, and Astra maintained monopoly power in each relevant market during that time period.

MARKET EFFECTS

- 26. The acts and practices of Astra, as herein alleged, had the purpose and effect of restraining competition unreasonably and injuring competition by protecting TOPROL-XL® from generic competition in the relevant market.
- 27. If a generic competitor had been able to enter the relevant market and compete with Astra, End-Payors such as Plaintiff would have been free to substitute a lower-priced generic for the higher-priced brand name drug and the Class would have paid less for TOPROL-XL® products. Pharmacists generally are permitted, and in some instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. In addition, there is a ready market for generic products because certain third-party payors of prescription drugs (e.g., managed care plans) encourage or insist on the use of generic

drugs whenever possible. A generic product can quickly and efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year.

28. By preventing generic competitors from entering the market, Astra injured Plaintiff and the other Class members in their business or property by causing them to pay more for TOPROL-XL® than they otherwise would have paid. Astra's unlawful conduct deprived Plaintiff and other End-Payors of the benefits of competition that the antitrust laws and applicable state consumer protection laws were designed to preserve.

FACTUAL ALLEGATIONS

A. Federal Regulation of Prescription Drugs

1. Brand-name Drugs v. Generic Drugs

- 29. The laws governing pharmaceutical products are meant to balance the competing policy goals of providing new drug inventors an economic return on their investment while also ensuring consumers access to additional and more affordable generic versions of brand name drugs.
- 30. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. The U.S. market accounts for more than 40% of the world's prescription pharmaceutical revenues. The cost of prescription drugs in the United States has been rising at double digit rates for years.
- 31. The availability of generic drugs has been one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which also must be approved by the FDA, have the same active chemical composition and provide the same

therapeutic effects as the pioneer brand-name drugs upon which they are modeled. The FDA will assign an "AB" rating to generic drugs that are bioequivalent to pioneer or brand-name drugs.

- 32. To be deemed a therapeutic equivalent and assigned an "AB" rating by the FDA, the generic drug must contain the same active ingredient(s); dosage form and route of administration; and strength. If so, the generic drug, as a therapeutic equivalent, can be substituted (and in some instances must be substituted) for the pioneer or brand-name drug at the pharmacy dispensing the drug.
- 33. Drugs are generally priced substantially below the brand-name drugs to which they are bioequivalent. A 1998 study conducted by the Congressional Budget Office (the "CBO") concluded that generic drugs save consumers and third-party payors between \$8 billion and \$10 billion a year. A report prepared by the Government Accounting Office in August 2000 observed, "Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs."
- 34. The Federal Trade Commission ("FTC") estimates that the first generic manufacturer to enter the market typically charges between 70% and 80% of the price of the brand-name drug. As additional manufacturers bring generic versions of the drug to market, the price continues to drop.
- 35. A brand-name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition, even if the brand-name manufacturer lowers prices to meet competition. The 1998 CBO study estimates that

generic drugs capture at least 44% of the brand-name drug's market share in just the first year of sale.

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2. Prescriptions for Generic Drugs

- 37. Generic drugs are drugs that the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the pioneer, brandname drugs. Where a generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating.
- 38. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing the branded drug, or the ABrated generic at a lower price.
- 39. Once a physician writes a prescription for a brand-name drug such as TOPROL-XL®, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs which carry the FDA's AB generic rating may

be substituted by a pharmacist for a physician's prescription for a brand-name drug.

3. New Drug Applications (NDA)

- 40. The statute regulating the manufacture and distribution of drugs and medical devices in the United States is the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. (the "FD&C Act").
- 41. Under the FD&C Act, approval by the FDA, the governmental body charged with regulation of the pharmaceutical industry, is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 355(a). Pre-market approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 355(b) of the FD&C Act demonstrating that the drug is safe and effective for its intended use.
- 42. New drugs that are approved for sale in the United States by the FDA are typically covered by patents, which provide the patent owner with the right to exclude others from making, using or selling that new drug in the United States for the duration of the patents, plus any extension of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("Hatch-Waxman Act").
- 43. Pursuant to 21 U.S.C. § 355(b), in its NDA the pioneer drug manufacturer must list all patents that claim the drug for which FDA approval is being sought, or that claim a method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug.

- 44. Once the NDA is approved, any claimed patents are listed with the NDA in a publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations. This publication is commonly called the "Orange Book."
- 45. Pursuant to 21 U.S.C. § 355(c)(2), if, after its NDA is approved, the pioneer drug manufacturer is issued a new patent that claims the drug or methods of its use, the company must supplement its NDA by listing such new patent within 30 days of issuance, whereupon the FDA publishes the new patent in a supplement to the Orange Book. The FDA is required to accept as true patent information it obtains from patent holders, such as whether a patent covers a particular drug product. If an unscrupulous patent holder is willing to provide false information to the FDA to delay the onset of generic competition, the FDA is powerless to stop it.
- 46. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a doctor who writes a prescription specifying the drug, which must be purchased from a licensed pharmacist. Generally, the pharmacist must, in turn, fill the prescription with the drug specified by the physician unless a generic version is available that has been approved by the FDA for substitution as bioequivalent.

4. Abbreviated New Drug Applications ("ANDAs") For Generic Drugs

47. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. Consumers benefit from the choice and competition. To effectuate its purpose,

the Hatch-Waxman Act permits a generic drug manufacturer to file an Abbreviated New Drug Application ("ANDA"), which incorporates by reference the safety and effectiveness data developed and previously submitted by the manufacturer of the original, pioneer drug.

- 48. The Hatch-Waxman Act permits ANDA applicants to perform all necessary testing, submit an application for approval, and receive tentative approval before the relevant patents expire. Prior to the Hatch-Waxman Act, a generic applicant had to wait until all patents had expired prior to beginning the approval process or otherwise face an infringement suit.
- 49. The brand-name drug patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has 45 days to initiate a patent infringement suit against the applicant. *See* 21 U.S.C. § 355(j)(5)(5)(iii). If no action is initiated within 45 days, the process for FDA approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the ANDA is automatically postponed until the earliest of the expiration of the patents, the expiration of 30 months from the patent holder's receipt of notice of the Paragraph IV Certification, or a final judicial determination of non-infringement.
- 50. The ANDA must include information concerning the applicant's position vis-a-vis the patent that the pioneer drug manufacturer claims applies to the drug. Therefore, the ANDA filer must make one of four certifications:
 - a) that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");

- b) that the patent for the pioneer drug has expired (a "Paragraph II Certification");
- c) that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or
- d) that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification").
- 21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV Certifications.
- 51. Accordingly, brand-name drug patent holders need only to file a patent infringement lawsuit within 45 days of receipt of Paragraph IV Certification in order to automatically block an ANDA applicant's generic drug from entering the market for up to 30 months.
- 52. An improper Orange Book listing also has additional anti-competitive effects because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of exclusivity in relation to other generic manufacturers. 21 U.S.C. 355(j)(5)(B)(iv). This 180 day exclusivity against other generic competitors is awarded to the first Paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV certification. Absent an improper Orange Book listing, no Paragraph IV certification would be required and, thus, no generic company would receive 180-day exclusivity.

B. Astra's Unlawful Scheme to Thwart Generic Competition

1. Background and Overview Astra's Anti-competitive Conduct

- 53. In the early 1990's Astra obtained two patents claiming the active compound metoprolol succinate and sustained (or extended) release versions of the drug. Specifically, these patents were issued by the United States Patent Trademark Office ("PTO") as *United States Patent 5,001,161* (the "'161 Patent") and United States Patent 5,081,154 (the "'154 Patent"). Astra, in turn, utilized the '161 and '154 Patents to manufacture TOPROL-XL®.
- 54. Metoprolol succinate is a pharmacological compound used in the treatment of angina, hypertension, and congestive heart failure. It has been manufactured exclusively by Astra as a result of its illegally obtained '161 and '154 Patents. On information and belief, its sales for 2005 exceed \$1.3 billion for the United States market alone.
- 55. In early 2004 several pharmaceutical companies, including KV Pharmaceuticals ("KV"), Andrx Pharmaceuticals, LLC and Andrx Corporation ("Andrx"), and Eon Labs, Inc. ("Eon") (collectively "the Generics") filed a Paragraph IV ANDA application with the FDA to manufacture bio-equivalent versions of 25, 50, 100, and 200 mg versions of TOPROL-XL®. Shortly thereafter, in conformity with 21 U.S.C. § 355(j)(2)(B)(ii) each of the above-named manufacturers notified Astra of their respective Paragraph IV filings.
- 56. On or about February 21, 2004 Eon informed Astra that it had filed a Paragraph IV certification before the FDA seeking to manufacturer generic bio-equivalents of the 25, 50, 100, and 200 mg version of TOPROL-XL® (the "Eon Letter").

Shortly thereafter, Andrx and KV supplied Astra with similar notice letters. On information and belief, the Eon Letter specifically set forth several reasons that the '161 and '154 Patents were invalid, including but not limited to, that the patents were invalid based upon the doctrines of anticipation and obviousness.

In response the Eon's, and the other generics' decision to seek Paragraph 57. IV certification, Astra initiated suit to enforce the '161 and '154 Patents. The litigation was ultimately consolidated by the Judicial Panel for Multidistrict Litigation before the Eastern District of Missouri in the MDL styled In re Metoprolol Succinate Patent Litigations MDL No. 1620. At the time Astra initiated litigation against the Generics, it knew that its patent was invalid and that the sole basis for its litigation was to artificially extend the life of the illegally obtained '161 and '154 Patents. This knowledge stemmed from a variety of sources, including but not limited to the fact that Astra knew that the '161 and '154 Patents were both anticipated by and obvious in light of Claim 8 of United States Patent No. 4,780,318 (the "'318 Patent"). Worse, Astra was keenly aware that it had engaged in inequitable conduct during the prosecution of the '161 and '154 Patents before the PTO. Specifically, Astra intentionally withheld material information from the PTO regarding the actual inventor of the '161 and '154 Patents and that from October of 1985 through the fall of 1988 it was involved in litigation with a Swedish competitor, Lejus Medical over who invented metoprolol succinate. Armed with this knowledge, Astra engaged in full scale litigation with the Generics alleging that its Patents were valid. Astra's litigation to enforce its illegally obtained '161 and '154 Patents was sham litigation that precluded Plaintiff and the End-Payor class from obtaining lower cost generic versions of 25, 50, 100 and 200 mg TOPROL-XL®.

2. The Litigation Between Astra and the Generics and the MDL Court's Order Granting the Generics' Motion for Summary Judgment

- 58. As noted above, the litigation between Astra and the Generics was consolidated in the Eastern District of Missouri in *In re Metoprolol Succinate Patent Litigation MDL No. 1620*. After the case was transferred to that Court, the parties engaged in pre-trial discovery. In response to Astra's Complaint alleging infringement of the '161 and '154 Patents, the Generics asserted a variety of affirmative defenses related to the validity of Astra's '161 and '154 Patents. These defenses included, but were not limited to the following:
 - a) that the '161 and '154 Patents were invalid based on the doctrine of anticipation;
 - b) that the '161 and '154 Patents were invalid based on the doctrine of obviousness; and
 - c) that the '161 and '154 Patents were invalid because Astra had engaged in inequitable conduct before the PTO during the prosecution of the '161 and '154 Patents.
- 59. Ultimately, the Generics moved for Summary Judgment seeking an Order that the '161 and '154 Patents were unenforceable. On January 17, 2006, the MDL Court granted the Generics' Motion for Summary Judgment concluding as follows:
 - I find clear and convincing evidence that Astra's '161 patent and '154 patent are invalid on the basis of double patenting over the '318 patent. I also find clear and convincing evidence that the '161 patent is not entitled to priority to the '318 patent application filing date. As a consequence I find that the '161 patent is invalid as anticipated.

Finally, I find by clear and convincing evidence that the '161 patent and

'154 patent are unenforceable based on Astra's inequitable conduct in the prosecution of these patents in the United States Patent Trademark Office. Astra failed to disclose to the USPTO the material dispute it had with Lejus concerning inventorship of metoprolol succinate. The failure to disclose was done with an intent to deceive the patent examiner as to this material dispute. Astra failed to provide material information in order to avoid questions concerning Astra's ability to claim priority to the '318 patent application and to avoid potential prior art concerning metoprolol succinate.

See Order Granting Defendants' Eon's, KV's and Andrx's Motion for Summary Judgment at 2006 U.S. Dist. LEXIS 1328 at 76-77(emphasis supplied).1

a. Astra's efforts to "double patent" the '318 Patent

approved *United States Patent No. 4,780,318* (the "'318 Patent"). Ultimately, Claim 8 of the '318 Patent claimed a sustained release version of metoprolol succinate (the same compound Astra claimed in its '161 Patent). Specifically, "the Abstract of the '318 Patent stated that, '[t]he present invention relates to a new oral pharmaceutical composition having an improved release of the therapeutically active composition having an improved release of the therapeutically active composition having an improved release of the therapeutically active compound present therein, in the lower part of the gastro-intestinal duct" 2006 U.S. Dist. LEXIS 1328 at 15. The patent application further noted that the drug contemplated, "a slow but controlled release of the therapeutically active compound from the core by diffusion through the diffusion membrane occurs due to the difference in concentrations on each side of said

In reaching this conclusion, the MDL Court conducted an exhaustive review of the facts leading up to Astra's efforts to obtain the '161 and '154 Patents before the PTO. Portions of that evaluation are referenced herein. Where an allegation in this Complaint is tied directly to a conclusion reached by the MDL Court in its *Order Granting Defendants' Motion for Summary Judgment* it will be noted by citation to the Court's Order as 2006 U.S. Dist. LEXIS 1328 at ____. All other allegations are made upon information and belief.

membrane." 2006 U.S. Dist. LEXIS 1328 at 17.

- 61. In the end, Claim 8 of the '318 Patent claimed "a particular type of formulation to allow the slow and controlled release of metoprolol succinate in or near the colon." 2006 U.S. Dist. LEXIS 1328 at 19-20. This type of "slow and controlled release of metoprolol succinate in or near the colon" was the exact claims contemplated by the '161 and '154 Patents. In fact, the sole claim of the '161 patent contemplated "[a] sustained release pharmaceutical composition comprising metoprolol succinate together with a pharmaceutically acceptable carrier." See 2006 U.S. Dist. LEXIS 1328 at 21. To that end, '161 patent application concluded virtually and identical claim stating in the "Technical Field" that, "the object of the present invention is to obtain a therapeutically active compound intended to be released close to or within the colon, and particularly to such active compounds which are soluble in the pH range of 1 to 8." 2006 U.S. Dist. LEXIS 1328 at 20.
- 62. At the time the '318, '161 and '154 Patents were under review by the PTO, scientists skilled in art generally recognized that the term "sustained release" was interchangeable with the terms "extended release" and "controlled release." At all times relevant to this litigation, Astra knew that the terms "sustained release", "extended release" and/or "timed release" were interchangeable. In fact, after conducting an exhaustive review in the claims construction process, the Court concludes, "What is clear is that sustained, extended, or timed release dosages were deemed to be dosages that release more slowly over time than immediate release dosages." 2006 U.S. Dist. LEXIS 1328 at 28. In other words, the '161 and '154 Patents in tandem claimed nothing more

that a version of metoprolol succinate that was release over time in the body. Accordingly, because both Claim 8 of the '318 Patent and the '161 Patent contemplated the same thing, i.e., a controlled release of metoprolol succinate, the '161 Patent was precluded by the doctrine of obviousness. Similarly, the '154 Patent merely claimed metoprolol succinate -- a claim that was subsumed within Claim 8 of the '318 Patent which related to "certain pharmaceutical compositions containing metoprolol succinate." 2006 U.S. Dist. LEXIS 1328 at 34. As such, Claim 8 of the '318 Patent anticipated the claims in the '154 Patent.

b. The '161 Patent was "anticipated" by "prior art"

- 63. At the time Astra prosecuted the '161 Patent before the PTO it knew of the existence of the '318 Patent.
- 64. In an effort to avoid the prior art implications that '318 Patent had upon the '161 Patent, Astra contended that its patent was entitled to priority over the '318 Patent. However, the specification of the '318 Patent does not describe the '161 Patent invention with all of its limitations. As such, the '161 Patent was not entitled to priority over the '318 Patent.
- 65. On information and belief, at the time Astra prosecuted the '161 Patent it knew that its patent was not entitled to priority to the '318 Patent. Despite that, Astra intentionally withheld this information from the PTO (i.e., that the '318 Patent anticipated the '161 Patent). Worse, armed with the knowledge that the '318 Patent in fact anticipated the '161 Patent, Astra pressed forward with this litigation with the sole purpose to preserve its unenforceable patent.

c. Astra's inequitable conduct before the PTO

- 66. Perhaps the most egregious aspect of Astra's efforts to enforce its illegal patent is that occurred with Astra's full knowledge that it had misled the PTO during the prosecution of the '161 and '154 Patents. In short, at all times during its efforts to enforce the '161 and '154 Patents, Astra knew that the underlying litigation to enforce the patents between itself and the Generics was a sham to artificially extent the life of the patent.
- 67. From October of 1985 through the late fall of 1988, Astra engaged in litigation with a Swedish competitor named Lejus Medical. The crux of that litigation, which only came to light during the discovery process in the multidistrict litigation, involved who actually invented the claims articulated in the '161 and '154 Patents. Those claims are set forth in detail in the MDL Court's *Memorandum and Order Granting Defendants' Motion for Summary Judgment, 2006 U.S. Dist. LEXIS 1328* and are incorporated by reference herein. Certain allegations are set forth in detail below to identify the fundamental disclosures Astra failed to make to the PTO.
- 68. Metoprolol was invented in the 1960s. In 1971, an Astra chemist named Toivo Nitenberg synthesized metoprolol succinate and recorded it in his lab notebook. This product became known as Astra's product Lopressor. 2006 U.S. Dist. LEXIS 1328 at 48..
- 69. In the 1980's Astra began research regarding the opportunity to create an extended release version of metoprolol. 2006 U.S. Dist. LEXIS 1328 at 49. At the time, two individuals named Curt Appelgren and Eva Eskilsson were a part of the working

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group to develop some form of extended release metoprolol. *Id.* In 1982, Appelgren and a colleague Ulf Johnson met with Urban Stenhede who was a chemist employed by Astra. Stenhede in turn asked another Astra chemist named Lars Lilljequist to assist in developing an extended release version of metoprolol. Ultimately, it was Lars Lilljequist who created metoprolol succinate. *See 2006 U.S. Dist. LEXIS 1328 at 49-50.*

- 70. In fact, both Appelgren and Eskilsson testified in their depositions that they did not know that Nitenberg had formed metoprolol succinate for Astra in 1971. Further, Eskillsson specifically indicated that she *never* made metoprolol succinate. Nor could she recall why she was named as the inventor and, on information and belief, clearly conceded that she was not. 2006 U.S. Dist. LEXIS 1328 at 51..
- 71. In December 1982, Appelgren left to form Lejus Medical. Eskilsson left shortly thereafter to join the company. On January 10, 1984 Lejus Medical filed patent application SE8400085 with the Swedish Patent Office that claimed application for an extended release version of metoprolol succinate. 2006 U.S. Dist. LEXIS 1328 at 51-52. One year later, Lejus filed the same application in the USPTO Application No. 690,197 which was ultimately issued as the '318 Patent on October 25, 1988. *Id.* Appelgren and Eskillsson were named as the inventors.
- 72. In response to Lejus's filing, Astra initiated litigation against Lejus contending that Lejus has appropriated trade secret information from Astra *and* that the actual inventor of an extended release version of metoprolol succinate was Toivo Nitenberg.
 - 73. For more than three years litigation raged between Astra and Lejus

regarding who was the actual inventor of an extended release version of metoprolol succinate. In fact, in connection with that litigation, Astra specifically took the position that Appelgren and Eskilsson were not the inventors of an extended release version of metoprolol succinate. 2006 U.S. Dist. LEXIS 1328 at 53.. Ultimately, Astra and Lejus entered into an agreement whereby Lejus agreed to file a new patent application and then assign the claims to Astra in return Astra agreed to withdraw its dispute pending before the Swedish Patent Office. A critical component of the agreement was that Lejus withdraw its contention that Appelgren and Eskilsson "invented" an extended release version of metoprolol succinate. Id. at 54.

- 74. Throughout the patent prosecution of the '161 and '154 Patents Astra failed to disclose to the PTO either: a) the correct inventor of the '161 and '154 Patents; and b) that it had engaged in a "prolonged dispute over inventorship of metoprolol succinate" to the PTO. 2006 U.S. Dist. LEXIS 1328 at 72-73.
- 75. The issue of inventorship and the litigation between Astra and Lejus was a material omission before the PTO in connection with the '161 and '154 Patents. Further, on information and belief, and as the MDL Court concluded in its *Order and Memorandum Granting Defendants' Motion for Summary Judgment*:

I do not believe that the question of whether to disclose the inventorship dispute was a close call. To find otherwise is to find that Astra's filing with the Swedish Patent Office and its three-year dispute with Lejus were pursued in bad faith.

Not only was the issue of the dispute of inventorship highly material, Astra had a strong incentive to not disclose the dispute. If a patent examiner had learned of the dispute and found Nitenberg to be the sole inventor of metoprolol succinate, the '897 patent application would not have been

entitled to priority to the January 1985 United States application, The effective filing date for the '897 patent application would have been March 25, 1988. As a consequence, Astra's metoprolol succinate patents may have been denied as anticipated by the prior art of the publication of Lejus' European application on July 17, 1985.2

I find by clear and convincing evidence that the inventorship dispute between Astra and Lejus was highly material and should have been disclosed to the USPTO during prosecution of the patents in suit. I also find by clear and convincing evidence that Astra's motivation to not reveal the dispute was great [sic] based on the risk of losing its metoprolol succinate inventions as anticipated by prior art. *The intent to deceive is clearly present.* After weighing materiality and intent I find that Astra's conduct was so culpable that its '161 and '154 patents are unenforceable.

See 2006 U.S. Dist. LEXIS 1328 at 75-76 (emphasis supplied).

76. Astra's efforts to litigate against the Generics was just another step in its plan to obtain and artificially maintain its illegal patent; the litigation against the Generics was sham litigation that artificially and illegally extended the life of the '161 and '154 patents causing Plaintiff and the Class to pay supra-competitive prices for extend release versions of metoprolol succinate.

3. Monopoly Powers

77. Through the anticompetitive conduct alleged herein, Astra were able to charge supracompetitive prices for metoprolol succinate, and thus, by definition, maintained monopoly power with respect to metoprolol succinate sold in the United States. To the extent that Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is all metoprolol succinate products - i.e., TOPROL-XL® (in all

² United States Patent Application No. 172,897 (the '897 application) became the '161 Patent.

its forms and dosage strengths), and bioequivalent metoprolol succinate products. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which metoprolol succinate is prescribed. For the entire period relevant to this case, Astra have been able to profitably maintain the price of their branded metoprolol succinate products well above competitive levels.

- 78. The relevant geographic market is the United States and its territories.
- 79. Astra's market share in the relevant market is and was 100% at all times.
- 80. Astra's actions are part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered or done by Astra's officers, agents, employees or representatives while actively engaged in the management of Astra's affairs.
- 81. Astra's illegal acts to prevent the introduction and/or dissemination into the U.S. marketplace of any generic version of TOPROL-XL® resulted in Plaintiff and the Class paying more than they would have paid for metoprolol succinate, absent Astra's illegal conduct.

4. Effects on Competition and Damages to Plaintiff and Class

- 82. Astra's exclusionary conduct has delayed or prevented the sale of generic metoprolol succinate in the United States, and unlawfully enabled Astra to sell TOPROL-XL® at artificially inflated prices. But for Astra's illegal conduct, generic competitors would have been able to successfully market generic versions of TOPROL-XL® tablets by at least January 18, 2005, and additional generic competitors would have entered the market thereafter.
 - 83. Astra's pattern and practice of delaying generic entry is exclusionary and

unreasonably restrains competition. To the extent that Astra had any valid business purpose for their conduct, that purpose could be served by means that are less restrictive of competition, and would at all events be outweighed by the anticompetitive effects of the conduct.

84. If manufacturers of generic metoprolol succinate had been able to enter the marketplace and effectively compete with Astra earlier, as set forth above, Plaintiff and other members of the Class would have substituted lower-priced generic metoprolol succinate for the higher-priced brand-name TOPROL-XL® for some or all of their metoprolol succinate requirements, and/or would have received discounts on some or all of their remaining TOPROL-XL® purchases.

CLASS ACTION ALLEGATIONS

- 86. Plaintiff brings this action on behalf of itself and as representatives of the following Class:
- 87. All end-payors throughout the United States and its territories who reside in an *Illinois Brick Repealer* state or territory who purchased and/or paid for TOPROL-XL® or generic versions of TOPROL-XL® during the period May 2, 2003 to the present (the "Class Period") for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class"). For purposes of the Class definition, persons and entities "purchased" TOPROL-XL® if they paid some or all of the purchase price.
- 88. Excluded from the Class are all Defendants, their officers, subsidiaries and affiliates; all government entities (except for government-funded employee benefit

plans); all persons or entities that purchased TOPROL-XL® for purposes of resale, or directly from the Defendant or their affiliates, and the judge in this case and any members of his/her immediate family.

- 89. Plaintiff seeks class certification pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure.
- 90. <u>Numerosity</u>: The members of the Class are so numerous that joinder of all members is impracticable. TOPROL-XL® had annual sales in 2004 in excess of \$1 billion. There were thousands, if not hundreds of thousands, of prescriptions written for the benefit of End-Payors (and/or their members, participants and beneficiaries). The Class members are identifiable, *inter alia*, from information and records that are required by law to be maintained by pharmacies, drugstores, pharmaceutical benefit managers, and managed care organizations.
- 91. <u>Commonality</u>: Common questions of law and fact exist as to all members of the Class and predominate over any questions, if any, that may affect only individual members. This is particularly true given the nature of Defendant's conspiracy which was generally applicable to the entire Class, thereby making appropriate relief with respect to the Class as a whole. Such conduct includes the Defendant's exclusionary and anticompetitive efforts: (i) in committing fraud on The United States Patent and Trade Office; (ii) in filing sham litigation; and (iii) converting the relevant market from one confronted with generic competition to one that is not for the sole purpose of monopolizing and attempting to monopolize the market for TOPROL-XL®.
 - a. Common questions of fact include, but are not limited to:

- 1) whether Defendant maintained or attempted to maintain monopoly power by delaying generic entry;
- 2) whether direct proof of Defendant's monopoly power is available, and if available, whether it is sufficient to prove Defendant's monopoly power without the need to also define a relevant market;
- 3) whether Defendant intentionally and unlawfully excluded competitors and potential competitors from the market for TOPROL-XL® and generic bio-equivalents to TOPROL-XL®; and
- 4) whether Plaintiff and the Class have been damaged and the aggregate amount of damages.
- b. Common questions of law include, but are not limited to:
 - 1) to the extent a relevant market or markets must be defined, what that definition is or those definitions are;
 - 2) whether Defendant's activities alleged herein have substantially affected interstate commerce;
 - 3) whether Defendant's litigation asserting infringement of the '161 and '154 patents were baseless; and
 - 4) whether Defendant engaged in sham litigation for the purpose of preventing competition.
- 92. <u>Typicality</u>: Plaintiff's claims are typical of the members of the Class, in that Plaintiff purchased and/or paid for TOPROL-XL® throughout the United States, including the Indirect Purchaser States, during the Class Period. Such purchases and payments were made for consumer consumption of TOPROL-XL®. Additionally, Plaintiff's claim is typical of the claim of the Class because Astra's conspiracy to effect an illegal monopoly *vis-à-vis* its sham patent litigation applied equally to each and every member of the Class. To that end, all Class members paid inflated cost for metoprolol extended release tablets due directly to Astra's efforts to deter, delay and/or defeat

generic entrants from entering the marketplace. As a direct and proximate result of Astra's conspiracy, Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

- 93. Adequacy: Plaintiff will fairly and adequately protect and represent the interests of the Class. The interest of the Plaintiff is not antagonistic to those of the Class. Further, Plaintiff's attorneys are skilled in the prosecution of complex class action antitrust litigation.
- 94. **Predominance**: The central allegations in this case revolve around Astra's illegal monopolistic conspiracy. Accordingly, the quantum of evidence required to establish Astra's culpability does not vary from Class member to Class member. These issues predominate over all other issues and include, but are not limited to: 1) whether Astra engaged in sham litigation to defend the '161 and '154 patents; 2) whether Astra's sham litigation resulted in formation of an illegal monopoly; and 3) whether "the addition or subtraction of any of the plaintiffs to or from the class [has] a substantial effect on the substance of quantity of the evidence offered" to establish liability.
- 95. <u>Superiority</u>: Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that it might not be practicable

to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

96. Manageability: Manageability will not be an impediment to certifying this case as a class action. Adequate procedures will be available not only to identify the potential class members, but also to determine the amount of overcharge damages to which each member of the class is entitled. This is particularly true because: 1) federal and state laws require certain organization (whom are customers of Defendants) including, pharmacies, drug stores, pharmacy benefit managers and managed care organizations; and 2) the amount of overcharge can be determined *vis-à-vis* excerpt testimony in a method that is generally applicable to the Class.

FIRST CAUSE OF ACTION

FOR COMPENSATORY AND MULTIPLE DAMAMGES UNDER THE ANTITRUST STATTUTES OF THE INDIRECT PURCHASER STATES

- 97. Plaintiffs repeat and reallege the proceeding and subsequent paragraphs as though set forth herein.
- 98. Defendant's conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize under the antitrust laws of the Indirect Purchaser States, as follows:
 - a. <u>Alabama</u>: The aforementioned practices of Defendant was in violation of the Alabama Code § 6-5-60, *et seq.*;
 - b. Alaska: The aforementioned practices of Defendant was in violation of Alaska Stat. 45.50.580(a) & (b);
 - c. Arizona: The aforementioned practices by Defendant was in violation of

- the Arizona Uniform State Antitrust Act, Ariz. Re. Stat. §§ 44-1401, et seq., and the Constitution of the State of Arizona, Article 14, § 15;
- d. <u>California</u>: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*;
- e. <u>District of Columbia</u>: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;
- f. <u>Florida</u>: The aforementioned practices by Defendants were and are in violation of the Florida Antrust Act, Fla. Stat. Ann. §§ 542.15, et seq.;
- g. <u>Hawaii</u>: The aforementioned practices by Defendants were and are in violation of the Hawaii Revised Statutes §§ 480-2, 480-3, and 480-4;
- h. <u>Iowa</u>: The aforementioned practices by Defendants were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);
- i. <u>Kansas</u>: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*;
- j. <u>Kentucky</u>: The aforementioned practices by Defendants were and are in violation of the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§367.110, *et seq.*;
- k. <u>Louisiana</u>: The aforementioned practices by Defendants were and are in violation of the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51:121, *et seq.*;
- 1. <u>Maine</u>: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statutes, Me. Rev. Stat. Ann. Tit. 10, §§ 1101, et seq.;
- m. <u>Massachusetts</u>: The aforementioned practices by Defendants were and are in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93;
- n. <u>Michigan</u>: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform At, Mich. Comp. Laws §§ 445.771, et seq.;
- o. <u>Minnesota</u>: The aforementioned practices by Defendants were and are in

- violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, et seq.;
- p. <u>Mississippi</u>: The aforementioned practices by Defendant were and are in violation of the Mississippi antitrust statute, Miss. Code Ann. §§ 75-21-1, et seq.;
- q. Nebraska: The aforementioned practices by Defendant were and are in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601, et seq.;
- r. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, et seq., and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, et seq.;
- s. New Jersey: The aforementioned practices by Defendants were and are in violation of the New Jersey Antitrust Act, N.J. Stat. Ann. §§ 56:9-1, et seq.;
- t. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, et seq.;
- u. New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, et seq.;
- v. <u>North Carolina</u>: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust law, N.C. Gen. Stat. §§ 75-1, *et seq.*;
- w. North Dakota: The aforementioned practices by Defendants were and are in violation of North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, et seq.;
- x. <u>South Dakota</u>: The aforementioned practices by Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.*;
- y. <u>Tennessee</u>: The aforementioned practices by Defendants were and are in violation of Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, et seq.;

- z. <u>Vermont</u>: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act. Vt. Stat. Ann. Tit. 9, §§ 2451, et seq.;
- aa. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, et seq., and the West Virginia Consumer Credit and Protection Act. W. Va. Code §§ 46A-6-101, et seq.; and
- bb. <u>Wisconsin</u>: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, et seq., and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, et seq.
- 99. As a direct and proximate result of Defendant's violation of the aforementioned statutes, Plaintiff and the Class have been injured in an amount to be proven at trial.

SECOND CAUSE OF ACTION

FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR ASTRA' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

- 100. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.
- 101. As described above, Astra knowingly and willfully engaged in a course of conduct designated to improperly obtain and extend their monopoly power in the Relevant Market. This course of conduct included, *inter alia*, the following acts: (i) the prosecution of baseless, sham patent litigation(s) against a potential generic manufacturer(s), (iii) the intentional conversion of the relevant market from one confronting generic competition to one that is not, and (iv) the intentional frustration of generic competition by effectively eliminating the ability for a generic therapeutic

equivalent to be substituted for a TOPROL-XL® product. The result of Astra's unlawful conduct has been to obtain and extend their monopoly.

- 102. Astra intentionally and wrongfully created and maintained a monopoly power in the Relevant Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.
- 103. Plaintiffs and the other members of the Class have been injured in their business or property by reason of Astra's antitrust violation alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic versions of TOPROL-XL®, and paying higher prices for such products than they would have paid in the absence of the antitrust violation. The injury to Plaintiffs and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Astra's unlawful conduct.
- 104. Plaintiffs and the Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Astra's conduct in seeking to prevent competition as described herein violates Section 2 of the Sherman Act.
- 105. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anti-competitive market effects caused by the unlawful conduct of Astra, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

THIRD CAUSE OF ACTION

FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE

TRUST FOR UNJUST ENRICHMENT BY ASTRA

- 106. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.
- 107. As a result of their unlawful conduct described above, Astra has been and will continue to be unjustly enriched. Specifically, Astra has been unjustly enriched, to the detriment of the Plaintiffs and the Class by the receipt of, at a minimum, unlawfully inflated prices and/or illegal monopoly profits on their sale of TOPROL-XL®.
- 108. Astra has benefited from their unlawful acts and it would be inequitable for Astra to be permitted to retain any of their ill-gotten gains resulting from the overpayments for TOPROL-XL® made by Plaintiffs and the Class.
- 109. Plaintiffs and members of the Class are entitled to the amount of Astra's ill-gotten gains resulting from Astra's unlawful, unjust and inequitable conduct. Plaintiffs and the Class are entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiffs and the Class members may make claims on a *pro rata* basis.

WHEREFORE, Plaintiffs pray that:

- a) the Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure and specifically certify the Class of indirect purchaser set forth above;
- b) Plaintiffs and each member of the Class be awarded damages and, where applicable, treble, multiple, and other damages, according to the laws o the Indirect Purchaser States, including interest;
- c) the conduct alleged herein be declared, adjudged and decreed to be

in violation of Section 2 of the Sherman Act, of the statutes of the Indirect Purchaser States set forth above, and the common law of unjust enrichment;

- d) Defendants be enjoined from continuing the illegal activities alleged herein;
- e) Plaintiffs and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and
- f) Plaintiffs and the Class be granted such other and further as the Court deems just and necessary.

JURY DEMAND

Plaintiffs demand a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues to triable.

Date: February 23, 2006 CHIMICLES & TIKELLIS LLP

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Attorneys for Plaintiffs and the Proposed Class

≈JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

(22211				
I. (a) PLAINTIFFS] ALLIANCE	NATIONAL JOINT POWERS	HASSLE, A	ASTRAZENECA A STRAZENECA LP JTICALS LP	AB, AKTIEBOLAGET, and ASTRAZENECA
` '	of First Listed Plaintiff Todd County CCEPT IN U.S. PLAINTIFF CASES)	County of Residence	of First Listed Defendant (IN U.S. PLAINTIFF CASES OF ID CONDEMNATION CASES, US INVOLVED.	·
	Address, and Telephone Number) 302-656-2 ikellis LLP, one Rodne ngton, Delaware 19801	Attorneys (If Known)		
	ICTION (Place an "X" in One Box Only)	III. CITIZENSHIP OF I	PRINCIPAL PARTIES	Place an "X" in One Box for Plaintiff
□ 1 U.S. Government Plaintiff	**X Federal Question (U.S. Government Not a Party)		PTF DEF D 1 Incorporated or Pri of Business In This	
☐ 2 U.S. Government Defendant	☐ 4 Diversity (Indicate Citizenship of Parties in Item III)	Citizen of Another State C	O 2 Incorporated and P of Business In A	
		Citizen or Subject of a C Foreign Country	D 3 G 3 Foreign Nation	□ 6 □ 6
IV. NATURE OF SUIT	(Place an "X" in One Box Only) TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
CONTRACT 110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excl. Veterans) 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise REAL PROPERTY 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability	PERSONAL INJURY □ 310 Airplane □ 315 Airplane Product Liability □ 320 Assault, Libel & PERSONAL INJUR □ 362 Personal Injury Med. Malpractice Med. Malpractice Product Liability Product Liability	ACY 610 Agriculture 620 Other Food & Drug 625 Drug Related Scizure of Property 21 USC 881 630 Liquor Laws 640 R.R. & Truck 650 Airline Regs. 660 Occupational Safety/Health 690 Other 10 Fair Labor Standards Act 720 Labor/Mgmt. Relations 730 Labor/Mgmt. Reporting & Disclosure Act 740 Railway Labor Act 740 Railway Labor Act 740 Railway Labor Litigation 791 Empl. Ret. Inc. Security Act 10 Fair Labor Litigation 10 Fa	422 Appeal 28 USC 158 423 Withdrawal	400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 470 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit 490 Cable/Sat TV 810 Selective Service 850 Securities/Commodities/Exchange 875 Customer Challenge 12 USC 3410 890 Other Statutory Actions 891 Agricultural Acts 892 Economic Stabilization Act 893 Environmental Matters 894 Energy Allocation Act 895 Freedom of Information Act 900Appeal of Fee Determination Under Equal Access to Justice 950 Constitutionality of State Statutes
XEX Original □ 2 F	Cite the U.S. Civil Statute under which you to 15 U.S.C. \$2	Reinstated or anot Reopened (speciare filing (Do not cite jurisdiction		Judgment
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VII. REQUESTED IN COMPLAINT:	XX CHECK IF THIS IS A CLASS ACTIO UNDER F.R.C.P. 23	N DEMAND \$	CHECK YES only JURY DEMAND:	if demanded in complaint: : YSYYes □ No
VIII. RELATED CAS IF ANY	(See instructions): JUDGE GMS		DOCKET NUMBER 0 6	3, 06-71, 06-79, -93, 06-81, 06-10
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RECEIPT#	AMOUNT APPLYING IFP	JUDGE	MAG. JUI	DGE

AO FORM 85 RECEIPT (REV. 9/0/	`

United States District Court for the District of Delaware

06 116-Civil Action No. _____

ACKNOWLEDGMENT OF RECEIPT FOR AO FORM 85

NOTICE OF AVAILABILITY OF A UNITED STATES MAGISTRATE JUDGE **TO EXERCISE JURISDICTION**

EREBY ACKNOWLEDGE R	ECEIPT OF COPIES OF AO FORM 85.
FEB 2 3 2006	Many & Randoll I
(Date forms issued)	(Signature of Party or their Representative)
	DANNY P RANDOCPH JR.
	(Printed name of Party or their Representative)

Note: Completed receipt will be filed in the Civil Action